

Application Number 10/731,867

Amendment in response to Office Action mailed September 7, 2007

### **REMARKS**

This Amendment is responsive to the Office Action dated September 7, 2007. Applicant has amended claims 1, 12-17 and 28-30, and canceled claims 11, 23, 24, 26 and 27. Support for the amendments may be found throughout Applicant's originally-filed Application, including, for example, paragraphs [0010], [0050], and claim 12. Upon entry of this Amendment, claims 1-10, 12-22, 28-31, 33 and 34 are pending.

In view of the above amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the Office Action.

### **Information Disclosure Statement**

Applicant respectfully directs the Examiner's attention to the Information Disclosure Statements filed June 16, 2005, February 15, 2006 and August 16, 2007.

On the returned form 1440 for the Information Disclosure Statement filed June 16, 2005, the Examiner did not sign, and instead struck through, the reference numbered H1465 by Stokes. However, the Examiner did not provide any indication in any of the Office Actions as to why this reference was not considered. Applicant resubmits this reference in a new Information Disclosure Statement that accompanies this Amendment. Applicant respectfully requests that the Examiner consider this reference, and demonstrate consideration by initialing the corresponding box in the new Information Disclosure Statement. In the alternative, Applicant respectfully requests a statement explaining why the Examiner does not believe that these documents should be considered.

For the Information Disclosure Statement filed on February 15, 2006, there is one U.S. Patent listed. For the Information Disclosure Statement filed August 16, 2007, under "OTHER DOCUMENTS," Applicant included a reference to "Answers.com, [www.answers.com](http://www.answers.com), defined: discrete components, accessed on 3/2/07 (2 pages)."

The Examiner did not initial either reference on the Information Disclosure Statements with respect to these documents, nor did the Examiner include in the Office Action any reason for not considering these documents. Applicant respectfully requests that the Examiner consider these documents and demonstrate consideration by initialing the corresponding box of each

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Information Disclosure Statement. In the alternative, Applicant respectfully requests a statement explaining why the Examiner does not believe that these documents should be considered.

### **Objection to Declaration**

The Office Action indicated the oath or declaration is defective, and indicated that a new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date was required. Applicant respectfully traverses the objection to the Declaration. The basis for the objection to the Declaration as-filed is plainly in error.

The Office Action indicated that the Declaration is defective because it does not state that the person making the Declaration acknowledges "the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 C.F.R. 1.56." In particular, the Office Action suggested that the Declaration is defective because it reads as:

"I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56." (emphasis added)

rather than:

"I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56."

Hence, the Office Action objects merely to the insertion of "the" prior to patentability. This objection lacks merit. Applicant's statement and the purportedly "correct" statement differ only in the inclusion of the term "the" prior to patentability. In substance, both statements are exactly identical, and carry exactly the same meaning. Applicant notes that 37 C.F.R. § 1.56 repeatedly uses the phrase, "material to the patentability." The Office Action provided no support for the assertion that the Declaration would be defective because of the presence of "the" prior to "patentability." Applicant respectfully requests withdrawal of the objection to the Declaration.

### **Amendments to the Specification**

Applicant has amended the specification, as shown above, to include patent application serial numbers for the applications referenced in the specification, as requested by the Examiner.

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**Claim Rejections Under 35 U.S.C. § 103(a)**

The Office Action rejected claims 23-24 and 26-27 under 35 U.S.C. § 103(a) as being unpatentable over Sanchez-Zambrano (U.S. Patent No. 5,895,414), and also rejected claims 23, 24, 26, and 27 under 35 § 103(a) as being unpatentable over Probst et al. (U.S. Patent Application Publication No. 2003/0017372, hereinafter Probst). The Office Action also rejected claims 1-11, 13-14, 16-22, 28-31 and 33-34 under 35 U.S.C. § 103(a) as being unpatentable over Fischell (U.S. Patent No. 3,888,260) in view of Probst, and claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of Probst as applied to claims 1 and 13 above, and further in view of Faltys et al. (U.S. Patent No. 6,308,101, hereinafter Faltys). Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

***Claims 23, 24, 26 and 27***

Applicant does not agree with or acquiesce in any aspect of the rejections of claims 23, 24, 26 and 27. Nonetheless, in this Amendment, Applicant has canceled claims 23, 24, 26 and 27, without prejudice or disclaimer, for the purpose of expediting the prosecution of this application. As such, the rejections of claims 23, 24, 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Sanchez-Zambrano or Probst are moot.

***Claims 1-11, 13-14, 16-22, 28-31, 33, and 34***

In support of the rejection of independent claims 1 and 30 as previously presented, the Office Action cited Fischell in view of Probst. The Office Action characterized Fischell as disclosing an IMD comprising a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings. The Office Action also characterized Fischell as disclosing that the IMD comprises pulse generation circuitry to deliver a stimulation therapy to a brain of a patient, which the Office Action equated to Applicant's therapy delivery element, and control electronics to control the delivery of the stimulation. The Office Action further characterized Fischell as disclosing an overmold, which comprises flexible Silastic compound 19a, a stainless steel outer can 18 and flexible coating 27. The Office Action acknowledged that Fischell does not disclose that a surface of the overmold is concave along two

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axes prior to manipulation of the IMD such that the surface is adapted to be implanted proximate to a cranium of the patient. The Office Action looked to Probst in an attempt to overcome these deficiencies of Fischell, and cited Probst as teaching a device including a housing, read as an overmold, where at least a first surface is concave along multiple axes prior to manipulation of the device such that the surface is adapted to be implanted proximate to a cranium. The Office Action the stated it would have been obvious to modify Fischell in view of Probst to provide a device including a concave housing and a concave overmold to facilitate implantation of the device proximate a cranium of a patient without undo excavation of the implant site as taught by Probst.

While Applicant respectfully disagrees with the Office Action's assertion of non-patentability of claims 1 and 30, Applicant has amended claims 1 and 30 to clarify the claimed subject matter and expedite prosecution of the pending Application.

For example, claim 1 as amended is directed to an implantable medical device including a plurality of interconnected modules. At least one of the modules includes a metallic housing. The device further includes an overmold that at least partially encapsulates each of the modules, a therapy delivery element to deliver a therapy to a brain of a patient, and control electronics to control delivery of the therapy by the therapy delivery element. The therapy delivery element and control electronics are located within one of the modules. The modules are horizontally distributed at respective locations of the overmold and separately encapsulated by the overmold. The overmold is formed such that a surface of the overmold is concave along at least one axis prior to manipulation of the implantable medical device such that the surface is adapted to be implanted proximate to a cranium of the patient. Additionally, the overmold does not encapsulate at least a portion of the metallic housing.

Claim 30 as amended is directed to an implantable medical device including a plurality of interconnected modules, at least one of the modules comprising a metallic housing. The implantable medical device further includes a flexible overmold that at least partially encapsulates each of the modules, a therapy delivery element to deliver a therapy to a brain of a patient, and control electronics to control the delivery of the therapy by the therapy delivery element. The therapy delivery element and control electronics are located within one of the modules. The overmold is formed such that a surface of the overmold that is adapted to be

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implanted proximate to a cranium of the patient is concave along at least one axis prior to manipulation of the implantable medical device. The flexible overmold is configured to allow relative motion between the plurality of interconnected modules.

Fischell in view of Probst fails to disclose or suggest various elements of amended claims 1 and 30. For example, with respect to claim 1, Fischell in view of Probst fails to disclose or suggest an implantable medical device include an overmold that at least partially encapsulates each of the modules, and does not encapsulate at least a portion of the metallic housing.

Instead, according to the Office Action's interpretation, Fischell discloses an overmold that includes a flexible Silastic compound 19a, a stainless steel outer can 18 and a flexible coating 27. This "combined overmold" fully encapsulates the battery 19 and inner casing 13 disclosed by Fischell. Fischell discloses that one purpose of the combined overmold is to provide a hermetic seal which prevents the possibility of body fluids from damaging the enclosed components. There is no suggestion that either the battery or the inner can may only be partially encapsulated by the overmold. In fact, Fischell discloses that one of the objects of the invention is to provide double hermetic sealing.<sup>1</sup> Because of the disclosed double hermetic seal function of the overmold, a person having ordinary skill in the art would not have been motivated to modify Fischell to include a overmold that does not encapsulate at least a portion of at least one of the modules. Probst does not provide any disclosure sufficient to overcome this directly contrary teaching of Fischell.

With respect to claim 30, Fischell in view of Probst fails to disclose or suggest an implantable medical device that includes a flexible overmold that is configured to allow relative motion between the plurality of interconnected modules.

As discussed above, the Office Action asserts that the overmold of Fischell includes a stainless steel outer can 18, which is filled with a flexible Silastic compound 19a. Fischell does not disclose that this "overmold" allows any relative motion between the interconnected modules, e.g., between battery 19 and inner can 13. In fact, the Fischell overmold includes stainless steel outer can 18, which is inflexible. Thus, the Fischell overmold is clearly not configured to allow relative motion between the modules in the Fischell device.

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<sup>1</sup> Fischell, Col. 1, l. 59 to Col. 2, l. 3.

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Although itself a presumably flexible material, silastic compound 19a would not allow any relative motion of the battery 19 with respect to any of the other modules in the device of Fischell. This is because the silastic compound 19a is located within stainless steel outer can 18, which is inflexible. As discussed above, Fischell teaches away from any modification of its device that would result in removal or modification of the stainless steel outer can 18.

Furthermore, Fischell discloses that the inner can 13 is permanently connected to end cap 15 by, for example, electron beam welding.<sup>2</sup> The end cap 15, then, mates with and seals outer casing 18.<sup>3</sup> In this way, the inner can 13 is indirectly connected to the outer casing 18, and is not allowed motion relative to any other module within the device. Thus, it is clear that Fischell fails to disclose or suggest a flexible overmold that allows relative motion between the plurality of interconnected modules.

Claims 2-10, 12-22, 28 and 29 and claims 31, 33 and 34 depend from claims 1 and 30, respectively, and are thus in condition for allowance for at least the reasons presented above with respect to claims 1 and 30. Additionally, the dependent claims introduce limitations that are neither disclosed nor suggested by the applied references.

For example, the applied references fail to disclose or suggest an implantable medical device that includes an overmold that has a surface that is concave along two axes, as required by claim 2. In the Office Action's Response to Arguments section, the Office Action stated that figures 6-8 of Probst are identical to those shown in Applicant's Figures 8A-8B and 9A-9B, and that the Examiner is unsure how Applicant's figures show concavity along two axes, while Applicant argues that the figures of Probst show concavity along only one axis. Additionally, the Office Action argues that Probst expressly discloses that concavity may be along at least three axes.

Applicant respectfully disagrees with the Office Action's characterization of Probst and Applicant's own disclosure. For example, the embodiments shown in Figures 6-8 of Probst and Figures 8A-8B and 9A-9B of Applicant's specification are not identical, or even substantially the same. Figures 6-8 of Probst show three embodiments of housings having contoured or curved side walls. In contrast, Applicant's Figures 8A and 8B are two cross-sectional views of the same

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<sup>2</sup> Fischell, Col. 4, ll. 49-52.

<sup>3</sup> *Id.* at Col. 4, ll. 53-62.

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modular implantable medical device (IMD 100 of FIG. 7B) taken along two axes (axes 104 and 106).<sup>4</sup> Thus, it is clear that Applicant's FIGS. 8A and 8B are substantially different from Figures 6-8 of Probst, because Applicant's FIGS. 8A and 8B are illustrating two cross-sectional views taken along different axes of the same device, while Figures 6-8 of Probst illustrate various, different embodiments of a device.

Furthermore, none of individual Figures 6, 7 or 8 (or the accompanying description) of Probst discloses concavity along more than one axis. The Office Action apparently regarded curvatures R2, R3 and R4 of FIG. 7 as curvature along three axes. Applicant respectfully disagrees with this characterization of Probst. Curvatures R2, R3 and R4 of FIG. 7 are not curvatures along more than one axes, but merely different radii of curvature along the same axis (e.g., the axis extending in the horizontal direction of FIG. 7 in the plane of the figure). Probst makes no suggestion that the curvature is along two axes. Fischell provides no disclosure sufficient to overcome the deficiencies of Probst.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-10, 13, 14, 16-22, 28-31, 33 and 34 under 35 U.S.C. § 103(a). Withdrawal of this rejection is respectfully requested.

#### **Rejection for Obviousness-type Double Patenting:**

The Office Action rejected claims 1-10, 12-24, 26-31 and 33-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 7,212,864. The Office Action also rejected claims 1-24, 26-31 and 33-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 17-55 of U.S. Patent No. 7,242,982.

A Terminal Disclaimer accompanies this Amendment. The disclaimer is made to expedite issuance and is not intended as an admission that any claim of the present application is the same or an obvious variant of those of U.S. Patent Nos. 7,212,864 and 7,242,982. This disclaimer obviates the double patenting rejections based on U.S. Patent Nos. 7,212,864 and 7,242,982.

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<sup>4</sup> Applicant's originally filed Application, para. [0063].

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The Office Action also provisionally rejected claims 1-24, 26-31 and 33-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23-31, 33-37, 39-40, 42-53 and 55-61 of copending Application No. 10/731,869 (Amended June 8, 2007). Applicants note the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied.

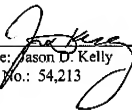
### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: January 3, 2008

By:

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<b>Form 1449*</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b>  (Use several sheets if necessary)	<b>Docket Number:</b> 1023-336US01		<b>Application Number:</b> 10/731,867	
	<b>Applicant:</b> Carl D. Wahlstrand; Darren A. Janzig; Ruchika Singhal; Robert M. Skime; Erik R. Scott; James E. Randall			
	<b>Filing Date:</b> December 9, 2003		<b>Group Art Unit:</b> 3766	
	<b>Examiner Name:</b> Jessica L. Reidel			

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Issue/Document Publication Date	Name	Filing Date If Appropriate
	3,720,874	03/13/1973	Gorcik et al.	
	4,934,368	06/19/1990	Lynch	
	5,220,929	06/22/1993	Marquit	
	5,480,416	01/02/1996	Garcia et al.	
	5,873,899	02/23/1999	Stutz, Jr. et al.	
	5,954,751	09/21/1999	Chen et al.	
	2002/0087201 A1	04/04/2002	Firlik et al.	
	2003/0120320 A1	06/26/2003	Solom	
	2004/0176815 A1	09/09/2004	Janzig et al.	

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Publication Date	Country	Translation	
				Yes	No
	2004/052459 A1	06/24/2004	PCT		

## OTHER DOCUMENTS (Including Authors, Title of Item, Page(s), Vol/Issue No., Publisher, Place of Publication)

	Answers.com, <a href="http://www.answers.com">www.answers.com</a> , defined: discrete components, accessed on 3/2/07 (2 pages).

EXAMINER

Date Considered

08/27/07

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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